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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,146	05/24/2002	Philip Braithwaite	2245/108	9521

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EXAMINER

DIXON, ANNETTE FREDRICKA

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,146	BRAITHWAITE, PHILIP	
	Examiner	Art Unit	
	Annette F. Dixon	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 4,21,23-25 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3,5-14,18-20,26-30 and 33-38 is/are allowed.
- 6) ☒ Claim(s) 15-17 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to **Claims 1 and 20** have been considered but are moot in view of both claims being amended.

Claim Rejections - 35 USC § 112

2. **Claims 16, 17 and 22** recites the limitation "said magazine" to hold the medicament, while the parent claim, **Claim 15**, uses a "spool." From a close reading of the specification on page 4, Lines 25-30, the Examiner believes the terms "spool" and "magazine" are essentially functional equivalents. Even so, there is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 15 and 16** are rejected under 35 U.S.C. 102(e) as being anticipated by Braithwaite (US Patent 5,778,873).

5. In regards to Claim 15 and 16, Braithwaite discloses a delivery device (40) comprising a rotatable metering member (41) adapted to dispense a measured amount of medicament material and comprising a spool and a spool carrier, a material delivery passage (45), a material delivery orifice (patient end of inhalation passage 45), at least one actuating member (46) adapted to move said metering member from a material retaining position (found in storage chamber 44) to a material dispensing position (found after material has been inhaled and enters waste chamber 49) characterized in that the actuator member moves in a substantially radial direction and actuates the metering member in said substantially radial direction and wherein the void between the spool and the spool carrier is filled with medicament. Regarding the metering member, as described by Braithwaite, "a chain (41) of [the] metering device is wound spirally around a central cylindrical core (42). Core (42) is able to rotate about axle (51). Chain (41) passes over a roller (43) through drug storage chamber (44) and then into inhalation passage (45)." (Please see Column 15, Lines 28-40). Regarding the spool and spool carrier, as shown in Figure 16, Braithwaite discloses a container (120) made of a series of units (121), each unit having a conduit (122) where in a spool (123) resides. Further, Braithwaite discloses the spool is "filled with a powdered drug, which occupies the space defined between the flanges (124), the neck (125), and the inner walls of the conduit (122). (Please see Column 18, Lines 27-50). Regarding the material delivery passage and orifice, Braithwaite discloses the material delivery passage (45) as an inhalation port; inherently, the material delivery orifice is the patient port or mouthpiece of the inhalation port. Regarding the actuating member, Braithwaite describes the

Art Unit: 3743

piston (46) as an actuator that moves the chain (41) containing the filled medicament. (Please see Column 15, Lines 28-40). Regarding the material retaining position and the material dispensing position, the medicament to be used during inhalation is stored in chamber (44), as the chain (41) is passed through the storage chamber (44) by the actuation of the piston (46) the rotatable metering member moves from a material retaining position to a material dispensing position once the chain (41) reaches the material delivery passage or inhalation port (45). Regarding the axial movement of the actuator and the metering member, the actuator (46) is acting against a spring (47), which intern results in the movement of the medicament; while the metering member (41) is moving in an axial direction around the core (42). **In regards to Claim 16**, the magazines or spools are filled with the medicament that is stored in the storage chamber (44).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 3743

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Braithwaite (US Patent 5,778,873) as applied to **Claim 15** above.

9. **In regards to Claim 17**, Braithwaite teaches a delivery device comprising all limitations recited in **Claim 17**, but does not expressly disclose the delivery device provided with a pair of magazines containing different medicaments. At the time the invention was made, it was well known in the art that patients may require two different medicaments to provide effective treatment and care of medical conditions. Therefore, it would have been obvious to one having ordinary skill in the art to have a pair of magazines containing different medicaments as the Applicant has done. Moreover, Applicant has not asserted that the specific multi-medicant dosing capability of the delivery device recited provides a particular advantage, solves a stated problem or serves a purpose different from that of providing allowing patients who require two different medicaments convenient packaging, thus the use of the pair of magazines containing different medicaments lacks criticality in its design.

10. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Braithwaite (US Patent 5,778,873) in view of Widerström (US Patent 6,698,425) as applied to **Claim 17**.

11. **In regards to Claim 22**, Braithwaite discloses an apparatus comprising all the limitations recited in **Claim 22**, with the exception of the medicaments characterized as

Art Unit: 3743

fluticasone and salmeterol. However, the use of fluticasone and salmeterol was known at the time the invention was made. Specifically, Widerström teaches the use of fluticasone and salmeterol in a powder inhaler as suitable medicaments. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the delivery device of Braithwaite by using the suitable medicaments of fluticasone and salmeterol because it is well known in the art, as taught by Widerström, to use these medicaments for use in a powder inhalers.

Allowable Subject Matter

12. **Claims 1-3, 5-14, 18-20, 26-29, 30, and 33-38** are allowed.

Obviousness-Type Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 3743

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **Claim 15** of the current applicant is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 2, and 4 of U.S. Patent No. 5,924,417. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose delivery devices with rotatable members containing receptacles for the delivery of medicament through the inhalation. Further the conflicting claims also recite the container comprising the rotatable members to be adapted for rotation inside the delivery device. These claimed elements are thus only obvious variants and can be practiced using the same apparatus.

15. **Claim 15** of the current applicant is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 12, 16, 18, and 19 of U.S. Patent No. 6,845,772. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose delivery devices with rotatable members containing medicament containers that are aligned to be within the same plane of the axis of rotation of the metering member. These claimed elements are thus only obvious variants and can be practiced using the same apparatus.

Conclusion

16. The following patent discloses a balance of prior art in the field of delivery devices with rotatable metering members. US 6,116,238.

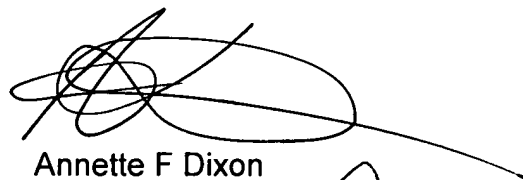
Art Unit: 3743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AFD



Annette F Dixon
Examiner
Art Unit 3743
March 2, 2006


Henry Bennett
Supervisory Patent Examiner
Group 3700